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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,982	08/23/2000	James A. St. Ville	2656-21	2642

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EXAMINER	
THANGAVELU, KANDASAMY	

ART UNIT	PAPER NUMBER
2123	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/643,982	ST. VILLE, JAMES A.	
	Examiner	Art Unit	
	Kandasamy Thangavelu	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-26,29-42,45 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-26,29-42,45 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *22 August 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Introduction

1. This communication is in response to the Applicants' Amendments dated May 31, 2005. Claims 1, 25 and 41 were amended. Claims 1-9, 12-26, 29-42, 45 and 56 of the application are pending in the application. This office action is made final.

Drawings

2. The drawings submitted on May 31, 2005 are accepted.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5 Claims 1, 4-9, 21-26 and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199).

5.1 **St. Ville** teaches a method and apparatus for manufacturing a prosthesis having optimized response characteristics. Specifically, as per Claim 1, **St. Ville** teaches a method for manufacturing an object having a potential { x } that is generated in response to a field { f } applied (Col 4, Lines 43-45 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49); and

specifying values for the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

calculating a material property matrix [k] based on the field { f } and potential { x } (Col 4, Lines 51-52);

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model (Col 4, Lines 53-55);

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials (Col 4, Lines 55-59);

determining manufacturing equipment control parameters for each volume increment of the object based on the matched material property coefficients (Col 4, Lines 59-61; Col 11, Lines 35-38; Col 13, Line 1-8; Lines 21-23); and

controlling the manufacturing equipment in accordance with the determined manufacturing equipment control parameters to thereby manufacture the object (Col 4, Lines 61-62; Col 12, Lines 13-18; Col 14, Lines 44-48);

wherein, if the material property coefficients correspond to a composite material, the manufacturing equipment control parameters comprises parameters for controlling composite manufacturing equipment (Col 6, Lines 52-58; Col 12, Lines 23-25; Col 12, Lines 39-42; Col 14, Lines 51-55);

and controlling of the manufacturing equipment comprises controlling composite manufacturing equipment (Col 6, Lines 52-58; Col 12, Lines 23-25; Col 14, Lines 51-58).

St. Ville does not expressly teach that the composite material comprises structural fibers laminated in a resin matrix. **Castanie et al.** teaches the composite material comprises structural fibers laminated in a resin matrix (Col 1, Lines 9-11; Col 1, Lines 14-21; Col 2, Line 67 to Col 3, Line 3), because this facilitates producing an article having high strength, accuracy and temperature resistance characteristics (Col 1, Lines 11-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville I** with method of **Castanie et al.** that included the composite material comprising structural fibers laminated in a resin matrix. The artisan would have been motivated because that would facilitate producing an article having high strength, accuracy and temperature resistance characteristics.

St. Ville teaches determining variables for the respective volume increments of the object (Col 13, Lines 1-8 and 21-23). **St. Ville** does not expressly teach that the composite material comprises a resin matrix into which an impurity is introduced, the amount of impurity introduced into the resin matrix being controllably variable for the respective volume increments of the object. **Harada et al.** teaches that the composite material comprises a resin matrix into which an impurity is introduced (Col 1, Lines 14-22; Col 3, Lines 40-45), the amount of impurity introduced into the resin matrix being controllably variable for the respective volume increments of the object (Col 3, Lines 55-64; Col 18, Lines 28-39), as the impurities act as reinforcing materials (CL1, L21) and that provides a composite material having improved mechanical strength (Col 2, Lines 54-55). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Harada et al.** that included the composite material comprising a resin matrix into which an impurity was introduced, the amount of impurity introduced into the resin matrix being controllably variable for the respective volume increments of the object. The artisan would have been motivated because the impurities would act as reinforcing materials and that would provide a composite material having improved mechanical strength.

5.2 As per Claim 4, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** also teaches generating of a computerized mathematical model of the object includes determining the smallest volume increment that can be manufactured using the manufacturing equipment. (Col 13, Lines 1-8 and Col 13, Lines 21-23).

5.3 As per Claim 5, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** also teaches that the field { f } is a mechanical force field and the potential { x } is a displacement. (Col 7, Lines 53-67).

5.4 As per Claim 6, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** also teaches that the field {f} is an electric current field and the potential { x } is a voltage. (Col 7, Lines 53-67).

5.5 As per Claim 7, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** also teaches that the field {f} is a magnetic field and the potential { x } is a magnetic vector potential. (Col 7, Lines 53-67).

5.6 As per Claim 8, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** also teaches that the field {f} is a thermal flux field and the potential { x } is a temperature. (Col 7, Lines 53-67).

5.7 As per Claim 9, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** also teaches that the field { f } is a fluid velocity field and the potential {x} is a fluid potential. (Col 7, Lines 53-67).

5.8 As per Claim 21, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** also teaches that the object being manufactured is a prosthetic implant for replacing

a body part and the field {f} and potential {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

5.9 As per Claim 22, **St. Ville, Castanie et al** and **Harada et al.** teach the method of Claim 1. **St. Ville** teaches an object made in accordance with the method of claim 1 (Col 6, Lines 58-62);

the object is selected from the group consisting of an automobile part, an aircraft part, a prosthetic implant, a golf club shaft, a tennis racket, a bicycle frame, and a fishing pole (Col 6, Lines 58-62); and

different portions of the object have different material properties corresponding to the matched extracted material property coefficients for known materials (Col 4, Lines 46-59).

5.10 As per Claim 23, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** teaches a prosthetic implant manufactured in accordance with the method of claim 1 (Col 8, Lines 23-35 and Col 8, Lines 39-44).

5.11 As per Claim 24, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** teaches a golf club manufactured in accordance with the method of claim 1. (Col 6, Lines 58-62).

5.12 As per Claim 25, **St. Ville** teaches a computer-implemented method for determining machine control instructions for manufacturing an object having a potential { x } that is generated in response to a field {f} applied (Col 14, Lines 44-48 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49); and

specifying values for the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

calculating a material property matrix [k] based on the force { f } and potential { x } (Col 4, Lines 51-52);

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model (Col 4, Lines 53-55);

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials (Col 4, Lines 55-59);

determining manufacturing equipment control parameters for each volume increment of the object based on the matched material property coefficients (Col 4, Lines 59-61; Col 11, Lines 35-38; Col 13, Line 1-8; Lines 21-23); and

generating machine control instructions for controlling the manufacturing equipment in accordance with the manufacturing equipment control parameters to y manufacture the object (Col 14, Lines 49-53);

wherein, if the material property coefficients correspond to a composite material, the manufacturing equipment control parameters comprises parameters for controlling composite manufacturing equipment (Col 6, Lines 52-58; Col 12, Lines 23-25; Col 12, Lines 39-42; Col 14, Lines 51-55);

and machine control instructions comprise instructions for controlling composite manufacturing equipment (Col 6, Lines 52-58; Col 12, Lines 23-25; Col 14, Lines 44-48; Col 14, Lines 51-58).

St. Ville does not expressly teach that the composite material comprises structural fibers laminated in a resin matrix. **Castanie et al.** teaches the composite material comprises structural fibers laminated in a resin matrix (Col 1, Lines 9-11; Col 1, Lines 14-21; Col 2, Line 67 to Col 3, Line 3), because this facilitates producing an article having high strength, accuracy and temperature resistance characteristics (Col 1, Lines 11-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville I** with method of **Castanie et al.** that included the composite material comprising structural fibers laminated in a resin matrix. The artisan would have been motivated because that would facilitate producing an article having high strength, accuracy and temperature resistance characteristics.

St. Ville teaches determining variables for the respective volume increments of the object (Col 13, Lines 1-8 and 21-23). **St. Ville** does not expressly teach that the composite material comprises a resin matrix into which an impurity is introduced, the amount of impurity introduced into the resin matrix being controllably variable for the respective volume increments of the object. **Harada et al.** teaches that the composite material comprises a resin matrix into

which an impurity is introduced (Col 1, Lines 14-22; Col 3, Lines 40-45), the amount of impurity introduced into the resin matrix being controllably variable for the respective volume increments of the object (Col 3, Lines 55-64; Col 18, Lines 28-39), as the impurities act as reinforcing materials (CL1, L21) and that provides a composite material having improved mechanical strength (Col 2, Lines 54-55). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Harada et al.** that included the composite material comprising a resin matrix into which an impurity was introduced, the amount of impurity introduced into the resin matrix being controllably variable for the respective volume increments of the object. The artisan would have been motivated because the impurities would act as reinforcing materials and that would provide a composite material having improved mechanical strength.

5.13 As per Claim 26, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 25. **St. Ville** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the field {f} and potential {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

5.14 As per Claim 38, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 25. **St. Ville** also teaches a computer system programmed to perform the method of claim 25 (Col 13, Line 53 to Col 14, Line 58 and Col 14, Lines 59-61).

5.15 As per Claim 39, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 25. **St. Ville** also teaches a control system programmed with machine control instructions for controlling composite manufacturing equipment to manufacture a composite object, where the machine control instructions are generated in accordance with the method of claim 25. (Col 12, Lines 23-25 and Col 12, Lines 39-42).

5.16 As per Claim 40, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 25. **St. Ville** also teaches composite manufacturing equipment comprising a control system programmed with machine control instructions for controlling the composite manufacturing equipment to manufacture a composite object, where the machine control instructions are generated in accordance with the method of claim 25. (Fig. 10; Col 12, Lines 39-42 and Col 15, Lines 28-42).

5.17 As per Claim 41, **St. Ville** teaches a method for manufacturing an object for which a defined field { f } generates a potential {x} in response (Col 14, Lines 44-48 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49);

specifying values of the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

calculating a material property matrix [k] based on the force { f } and potential { x } (Col 4, Lines 51-52);

wherein the material property matrix [k] comprises a plurality of values each corresponding to one or more material property coefficients (Col 4, Lines 53-59);

comparing each of the plurality of values in the material property matrix [k] to known material properties (Col 4, Lines 55-59);

responsive to a match, selecting a corresponding manufacturing process parameter for a volume increment of the object, wherein the selected manufacturing process parameter is usable for controlling composite manufacturing equipment if the matched known material property is a material property for a composite material (Col 4, Lines 59-61 and Col 12, Lines 23-25; Col 13, Line 1-8; Lines 21-23); and

controlling the composite manufacturing equipment in accordance with the selected manufacturing process parameters to thereby manufacture the object (Col 14, Lines 44-48).

St. Ville does not expressly teach that the composite material comprises structural fibers laminated in a resin matrix. **Castanie et al.** teaches the composite material comprises structural fibers laminated in a resin matrix (Col 1, Lines 9-11; Col 1, Lines 14-21; Col 2, Line 67 to Col 3, Line 3), because this facilitates producing an article having high strength, accuracy and temperature resistance characteristics (Col 1, Lines 11-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville I** with method of **Castanie et al.** that included the composite material comprising structural fibers laminated in a resin matrix. The artisan would have been motivated because that would facilitate producing an article having high strength, accuracy and temperature resistance characteristics.

St. Ville teaches determining variables for the respective volume increments of the object (Col 13, Lines 1-8 and 21-23). **St. Ville** does not expressly teach that the composite material comprises a resin matrix into which an impurity is introduced, the amount of impurity introduced into the resin matrix being controllably variable for the respective volume increments of the object. **Harada et al.** teaches that the composite material comprises a resin matrix into which an impurity is introduced (Col 1, Lines 14-22; Col 3, Lines 40-45), the amount of impurity introduced into the resin matrix being controllably variable for the respective volume increments of the object (Col 3, Lines 55-64; Col 18, Lines 28-39), as the impurities act as reinforcing materials (CL1, L21) and that provides a composite material having improved mechanical strength (Col 2, Lines 54-55). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Harada et al.** that included the composite material comprising a resin matrix into which an impurity was introduced, the amount of impurity introduced into the resin matrix being controllably variable for the respective volume increments of the object. The artisan would have been motivated because the impurities would act as reinforcing materials and that would provide a composite material having improved mechanical strength.

5.18 As per Claim 42, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 41. **St. Ville** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the field {f} and potential {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

6. Claims 56 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199) and **Wu et al.** (U.S. Patent 5,654,077).

6.1 As per claim 56, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** teaches that the method includes specifying the material properties of the finite elements (Col 4, Lines 51-52). **St. Ville** does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **Wu et al.** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as both **St. Ville** and **Wu et al.** deal with material properties of multimaterial laminate, and the symmetry eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Wu et al.** specifying that the material properties of the finite elements have a particular symmetry. The artisan would have been motivated because both **St. Ville** and **Wu et al.** deal with material properties of multimaterial laminate, and the symmetry would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

6.2 As per Claim 2, **St. Ville, Castanie et al, Harada et al.** and **Wu et al.** teach the method of Claim 56. **St. Ville** does not expressly teach that the material properties of the finite elements

are specified to be isotropic. **Wu et al.** teaches that the material properties of the finite elements are specified to be isotropic (Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with the method of **Wu et al.** that included the material properties of the finite elements being specified to be isotropic. The artisan would have been motivated because that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199), **Wu et al.** (U.S. Patent 5,654,077) and **Legere** (U.S. Patent 6,087,571).

7.1 As per Claim 3, **St. Ville, Castanie et al., Harada et al.** and **Wu et al.** teach the method of Claim 56. **St. Ville** does not expressly teach that the material properties of the finite elements are specified to be transversely isotropic. **Legere** teaches that the material properties of the finite elements are specified to be transversely isotropic (Col 6, Lines 55-65), so the material will have enhanced properties in the draw direction and properties similar to those of the undrawn polymer in all directions transverse to the draw direction (Col 6, Lines 53-55). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Legere** that specifies that the material properties of the finite

elements be transversely isotropic. The artisan would have been motivated because then the material would have enhanced properties in the draw direction and properties similar to those of the undrawn polymer in all directions transverse to the draw direction.

8. Claims 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199), and **Abatangelo et al.** (WO 97/18842).

8.1 As per Claim 12, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises biologic material. **Abatangelo et al.** teaches that the impurity comprises biologic material (Page 3, Para 4), since it is possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue (Page 2, Para 4). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Abatangelo et al.** that specifies that the impurity comprising biologic material. The artisan would have been motivated because it would be possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue.

8.2 As per Claim 29, it is rejected based on the same reasoning as Claim 12, supra. Claim 29 is a method claim reciting the same limitation as Claim 12, as taught throughout by **St. Ville, Castanie et al., Harada et al.** and **Abatangelo et al.**

9 Claims 13 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199) and **Johnson et al.** (U.S. Patent 6,296,667).

9.1 As per Claim 13, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises bone. **Johnson et al.** teaches that the impurity comprises bone (Col 6, Lines 13-25), since that provides an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair (Col 1, Lines 27-30) It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Johnson et al.** that specified that the impurity comprised bone. The artisan would have been motivated because that would provide an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair.

9.2 As per Claim 30 it is rejected based on the same reasoning as Claim 13, supra. Claim 30 is a method claim reciting the same limitation as Claim 13, as taught throughout by **St. Ville, Castanie et al., Harada et al.** and **Johnson et al.**

10. Claims 14 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199), and **Bonadio et al.** (U.S. Patent 5,942,496).

10.1 As per Claim 14, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises crushed bone. **Bonadio et al.** teaches that the impurity comprises crushed bone (Col 58, Lines 29-34), since this material has the ability to simulate new bone formation (Col 58, Lines 35-36). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Bonadio et al.** that specified that the impurity comprised crushed bone. The artisan would have been motivated because this material would have the ability to simulate new bone formation.

10.2 As per Claim 31, it is rejected based on the same reasoning as Claim 14, supra. Claim 31 is a method claim reciting the same limitation as Claim 14, as taught throughout by **St. Ville, Castanie et al., Harada et al.** and **Bonadio et al.**

11. Claims 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199) and **Warren, Jr.** (U.S. Patent 6,348,042).

11.1 As per Claim 15, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises co-factors. **Warren, Jr.** teaches that the impurity comprises co-factors (abstract; Col 2, Lines 38-52), as the cofactors activate the enzyme impregnated in the lumen, within the biological system (Col 3, Lines 10-12). It would

have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Warren, Jr.** that specified that the impurity comprised co-factors. The artisan would have been motivated because the cofactors activate the enzyme impregnated in the lumen, within the biological system.

11.2 As per Claim 32, it is rejected based on the same reasoning as Claim 15, supra. Claim 32 is a method claim reciting the same limitation as Claim 15, as taught throughout by **St. Ville, Castanie et al., Harada et al.** and **Warren, Jr.**

12. Claims 16 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199) and **Tadros et al.** (U.S. Patent 6,121,033).

12.1 As per Claim 16, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises biological cells. **Tadros et al.** teaches that the impurity comprises biological cells (Col 14, Lines 39-52), as biological cells are completely degradable into biomass without having toxic effect on the microbes (Col 14, Lines 41-43). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Tadros et al.** that specified that the impurity comprised biological cells. The artisan would have been motivated because biological cells are completely degradable into biomass without having toxic effect on the microbes.

12.2 As per Claim 33, it is rejected based on the same reasoning as Claim 16, supra. Claim 33 is a method claim reciting the same limitation as Claim 16, as taught throughout by **St. Ville, Castanie et al., Harada et al.** and **Tadros et al.**

13. Claims 17 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199) and **Slaikeu** (U.S. Patent 6,231,590).

13.1 As per Claim 17, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises bio-active materials. **Slaikeu** teaches that the impurity comprises bio-active materials (Col 7, Lines 15-21), since such materials have properties to reduce friction, provide a therapeutic for local or blood borne delivery and enhance thrombosis, coagulation or platelet activity (Col 7, Lines 8-11). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Slaikeu** that specified that the impurity comprised bio-active materials. The artisan would have been motivated because that would allow manufacturing including bio-active materials which would be useful to reducing friction, providing a therapeutic for local or blood delivery etc.

13.2 As per Claim 34, it is rejected based on the same reasoning as Claim 17, supra. Claim 34 is a method claim reciting the same limitation as Claim 17, as taught throughout by **St. Ville, Castanie et al., Harada et al.** and **Slaikeu.**

14. Claims 18 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199) and **Hermann** (U.S. Patent 5,098,621).

14.1 As per Claim 18, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises medications. **Hermann** teaches that the impurity comprises medications (Col 9, Lines 49-55), as medications could be dispensed for the dressings (Col 9, Lines 51-52). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Hermann** that specified that the impurity comprised medications. The artisan would have been motivated because that would allow medications to be dispensed for the dressings.

14.2 As per Claim 35, it is rejected based on the same reasoning as Claim 18, supra. Claim 35 is a method claim reciting the same limitation as Claim 18, as taught throughout by **St. Ville, Castanie et al., Harada et al.** and **Hermann.**

15. Claims 19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199) and **Phipps et al.** (U.S. Patent 6,289,242).

15.1 As per Claim 19, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises antibiotics. **Phipps et al.** teaches that the impurity comprises antibiotics (Col 16, Lines 46-50), since antibiotics could be introduced into the host for use as anti-infectives (Col 16, Lines 46-50). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with method of **Phipps et al.** that specified that the impurity comprised antibiotics. The artisan would have been motivated because antibiotics could be introduced into the host for use as anti-infectives.

15.2 As per Claim 36, it is rejected based on the same reasoning as Claim 19, supra. Claim 36 is a method claim reciting the same limitation as Claim 19, as taught throughout by **St. Ville, Castanie et al., Harada et al.** and **Phipps et al.**

16. Claims 20 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), and further in view of **Harada et al.** (U.S. Patent 5,563,199) and **Mavity et al.** (U.S. Patent 6,248,057).

16.1 As per Claim 20, **St. Ville, Castanie et al.** and **Harada et al.** teach the method of Claim 1. **St. Ville** does not expressly teach that the impurity comprises radioactive materials. **Mavity et al.** teaches that the impurity comprises radioactive materials (Col 2, Lines 1-5), since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer (Abstract). It would have been obvious to one of ordinary skill in the art at the time of

Applicant's invention to modify the method of **St. Ville** with method of **Mavity et al.** that specified that the impurity comprised radioactive materials. The artisan would have been motivated because they would be useful for a variety of medical purposes, being particularly suitable for treatment of cancer.

16.2 As per Claim 37, it is rejected based on the same reasoning as Claim 20, supra. Claim 37 is a method claim reciting the same limitation as Claim 20, as taught throughout by **St. Ville, Castanie et al., Harada et al.** and **Mavity et al.**

17. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville** (U.S. Patent 5,594,651) in view of **Castanie et al.** (U.S. Patent 6,290,889), **Harada et al.** (U.S. Patent 5,563,199), and further in view of **Abatangelo et al.** (WO 97/18842), **Johnson et al.** (U.S. Patent 6,296,667, **Bonadio et al.** (U.S. Patent 5,942,496), **Warren, Jr.** (U.S. Patent 6,348,042), **Tadros et al.** (U.S. Patent 6,121,033), **Slaikeu** (U.S. Patent 6,231,590), **Hermann** (U.S. Patent 5,098,621), **Phipps et al.** (U.S. Patent 6,289,242) and **Mavity et al.** (U.S. Patent 6,248,057).

17.1 As per Claim 45, **St. Ville, Castanie et al** and **Harada et al.** teach the method of Claim 41. **St. Ville** does not expressly teach that the impurity is selected from the group consisting of: biologic materials, bone, crushed bone, co-factors, biological cells, bio-active material, medications, antibiotics, and radioactive materials.

Abatangelo et al. teaches that the impurity is selected from biologic material (Page 3, Para 4), since it is possible to seed and grow fibroblasts enabling production of an extracellular

matrix similar to that of natural connective tissue (Page 2, Para 4). **Johnson et al.** teaches that the impurity is selected from bone (Col 6, Lines 13-25), since that provides an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair (Col 1, Lines 27-30). **Bonadio et al.** teaches that the impurity is selected from crushed bone (Col 58, Lines 29-34), since this material has the ability to simulate new bone formation (Col 58, Lines 35-36). **Warren, Jr.** teaches that the impurity is selected from co-factors (abstract; Col 2, Lines 38-52), as the cofactors activate the enzyme impregnated in the lumen, within the biological system (Col 3, Lines 10-12). **Tadros et al.** teaches that the impurity is selected from biological cells (Col 14, Lines 39-52), as biological cells are completely degradable into biomass without having toxic effect on the microbes (Col 14, Lines 41-43). **Slaikeu** teaches that the impurity is selected from bio-active materials (Col 7, Lines 15-21), since such materials have properties to reduce friction, provide a therapeutic for local or blood borne delivery and enhance thrombosis, coagulation or platelet activity (Col 7, Lines 8-11). **Hermann** teaches that the impurity is selected from medications (Col 9, Lines 49-55), as medications could be dispensed for the dressings (Col 9, Lines 51-52). **Phipps et al.** teaches that the impurity is selected from antibiotics (Col 16, Lines 46-50), since antibiotics could be introduced into the host for use as anti-infectives (Col 16, Lines 46-50). **Mavity et al.** teaches that the impurity is selected from radioactive materials (Col 2, Lines 1-5), since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer (Abstract).

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville** with

- the method of **Abatangelo et al.** that specified that the impurity was selected from biologic material, since it would be possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue;

- method of **Johnson et al.** that specified that the impurity was selected from bone, since that would provide an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair;

- method of **Bonadio et al.** that specified that the impurity was selected from crushed bone, since this material has the ability to simulate new bone formation;

- method of **Warren, Jr.** that specified that the impurity was selected from co-factors, as the cofactors activate the enzyme impregnated in the lumen, within the biological system;

- method of **Tadros et al.** that specified that the impurity was selected from biological cells, as biological cells are completely degradable into biomass without having toxic effect on the microbes;

- method of **Slaikeu** that specified that the impurity was selected from bio-active materials, since that would describe the manufacturing method for materials including bio-active materials which would be useful to reducing friction, providing a therapeutic for local or blood delivery etc;

- method of **Hermann** that specified that the impurity was selected from medications, since medications could be dispensed for the dressings;

- method of **Phipps et al.** that specified that the impurity was selected from antibiotics, since antibiotics could be introduced into the host for use as anti-infectives; and

- method of **Mavity et al.** that specified that the impurity was selected from radioactive materials, since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer.

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **St. Ville,** so the impurity is selected from the group consisting of: biologic materials, bone, crushed bone, co-factors, biological cells, bio-active material, medications, antibiotics, and radioactive materials, to achieve the desired benefits.

Response to Arguments

18. Applicant's arguments filed on May 31, 2005 have been fully considered. The arguments with respect to 103 (a) rejections of Claims 1, 25 and 41 are moot in view of the new ground(s) of rejection which are applied against the amended claims. The applicant's amendments necessitated the new grounds of rejection.

18.1 As per the applicant's argument that "claims 1, 25 and 41 have been amended to more specifically describe the claimed matrix as a "resin" matrix; the subject matter of these claims and the claims that depend therefrom would not have been rendered obvious by the proposed five-way combination of St. Ville, Castanie et al., Yamazaki et al., Johnson et al. and Phipps et al.; this combination does not disclose or suggest, among other things,

introducing an impurity into the resin matrix of a composite material as claimed", the examiner has used **Harada et al.** against the amended claims.

Harada et al. teaches that the composite material comprises a resin matrix into which an impurity is introduced (Col 1, Lines 14-22; Col 3, Lines 40-45), the amount of impurity introduced into the resin matrix being controllably variable for the respective volume increments of the object (Col 3, Lines 55-64; Col 18, Lines 28-39), as the impurities act as reinforcing materials (CL1, L21) and that provides a composite material having improved mechanical strength (Col 2, Lines 54-55).

18.2 As per the applicant's argument that "Applicant finds no disclosure in Castanie et al. of introducing impurities into the resin matrix of the composite material as claimed; ... Yamazaki actually teaches the desirability of avoiding the introduction of certain impurities and clearly does not teach or suggest introducing impurities as claimed; the other referenced portions of Yamazaki relate to using an impurity element in a crystalline silicon film in order to control the threshold voltage of a TFT; however, among other things, the crystalline silicon layer into which Yamazaki introduces Group 13 or Group 15 impurity elements is clearly not a resin matrix of a composite material as claimed; the semiconductor device of Yamazaki would not have fairly provided any relevant teaching or suggestion with respect to a resin matrix for a composite material in view of the significant differences between a semiconductor device (as in Yamazaki) and a composite material comprised of a resin matrix and structural fibers; in other words, it is not apparent how the knowledge obtained from Yamazaki that impurities can be implanted to

control the threshold voltage of a transistor would have provided any meaningful teaching or suggestion relevant to composite materials comprising a resin matrix and structural fibers", the examiner has used **Harada et al.** The applicant's attention is directed to Paragraph 18.1 above.

18.3 As per the applicant's argument that "Johnson et al. relates to bone substitutes and is applied for its alleged teaching of a matrix into which an impurity is introduced; ... Applicant does not find any of these references to "matrix" to disclose or even suggest a resin matrix of a composite material, much less the introducing of impurities into such a resin matrix as claimed", the examiner has used **Harada et al.** The applicant's attention is directed to Paragraph 18.1 above.

18.4 As per the applicant's argument that "Phipps et al. relates to the electrically assisted delivery of a therapeutic agent through a body surface such as a mucosal membrane; ... the matrix of Phipps et al. is clearly not a resin matrix and the disclosure of uniform dispersal of the drug does not teach or suggest the controllable variability aspect of claims 1, 25 and 41", the examiner has used **Harada et al.** The applicant's attention is directed to Paragraph 18.1 above.

Conclusion

ACTION IS FINAL

19. Applicant's amendments necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 571-272-3717. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard, can be reached on 571-272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to TC 2100 Group receptionist: 571-272-2100.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

K. Thangavelu
Art Unit 2123
August 11, 2005

Paul L. Rodriguez 8/18/05
Primary Examiner
Art Unit 2125